

Sterile Water Should Not be Given “Freely”

ABSTRACT

Severe hypernatremia can be challenging to treat. There appears to be a failure among healthcare practitioners to recognize the danger of infusing plain sterile water intravenously. Bags of sterile water for injection and inhalation also are being mistaken for intravenous (IV) solutions. Sterile water is hypotonic (0 mOsm/L). Serious patient harm, including hemolysis, can result when it is administered by direct IV infusion. PA-PSRS and other medication error reporting programs have received reports of IV administration of sterile water to patients, some of which have resulted in patient deaths. Risk reduction strategies include recognizing the problem, developing protocols to treat hypernatremia, establishing safeguards, assessing for safe storage, and ensuring that sterile water bags cannot be provided without prior pharmacy agreement and supervision. (Pa Patient Saf Advis 2008 Jun;5[2]:53-6.)

Severe hypernatremia, when the plasma concentration of sodium is greater than 145 mEq/L,¹ can be challenging to treat, especially in patients with conditions such as hyperglycemia that may seem to limit treatment options. It appears there is a failure among healthcare practitioners to recognize the danger of infusing plain sterile water intravenously to treat hypernatremia. Also, bags of sterile water for injection and inhalation are being mistaken for intravenous (IV) solutions when they are stocked on patient care units. Serious patient harm can result when sterile water is administered by direct IV infusion due to hemolysis related to the hypotonic nature of the product.

Sterile water for injection is sterile water that is intended to be used by pharmacy to compound IV products such as parenteral nutrition solutions. It also is used in small quantities to solubilize drugs—the drug solutes then contribute the osmotic pressure to the solution to keep it safe. To prepare isotonic IV solutions from sterile water for injection, solutes such as sodium chloride or dextrose may need to be added. It takes 9 g of sodium chloride or more than 50 g of dextrose in a liter of sterile water to make it isosmotic (about 308 mOsm/L) with blood. Potassium chloride is similar to sodium chloride—about 154 mEq/L in sterile water for injection is needed to be nearly isotonic. For cefazolin sodium, a 100 mg/mL solution in sterile water for injection is nearly isotonic. Sterile water for injection is 0 mOsm/L, which can be fatal. It should never be given intravenously to patients.

PA-PSRS and other medication error reporting programs have received reports of events involving the IV administration of sterile water to patients. There are two main reasons for these errors. First, healthcare

practitioners may have a knowledge deficit about the risks of IV administration of sterile water. For example, prescribers are ordering sterile “free water” to treat hypernatremia. Free water refers to water not associated with organic or inorganic ions. Because hypernatremia usually results from a loss of free water relative to solute, it is likely that prescribers intend to replace this deficit when writing these orders. Water can be replaced by mouth or nasogastric tube; however, if given intravenously without additives to normalize tonicity, hemolysis may occur. Second, inadvertent IV administration of sterile water is occurring due to the look-alike nature of bags of sterile water and other IV solutions.

Errors in the Prescribing Phase

In one particular event reported through PA-PSRS, a physician ordered 2 L of sterile water for injection to treat an intensive care unit (ICU) patient’s elevated sodium level.

Nurse was told to give the patient 2 L sterile water bolus IV for high sodium level. Nurse received IV sterile water from pharmacy. Nurse hung 1 L sterile water after getting order for doctor. Other doctor was aware of sterile water hanging. Nurse called pharmacist to receive second liter and was told it cannot be given IV. The infusion was stopped. The doctor was made aware.

The infusion was stopped in time to prevent any harm to the patient.

The Institute for Safe Medication Practices (ISMP) has reported a similar event in which a physician decided to give sterile water for injection intravenously to an elderly patient who had been admitted to an ICU with pneumonia, congestive heart failure, respiratory failure, severe hyperglycemia, and severe hypernatremia.² The physician was concerned about giving dextrose-containing fluids due to the patient’s hyperglycemia. The physician contacted a pharmacist, confirmed “large bags of sterile water for injection” were available, and changed the patient’s existing intravenous fluids to free water at 100 mL/hr. When he received the order, the pharmacist entered it into the computer. A pharmacy intern retrieved a bag from the sterile compounding area, placed the pharmacy-generated label on the back of the bag, and dispensed it to ICU. The nurse began the infusion without question because she was aware of the patient’s hypernatremia and overheard the physician ask the pharmacist if bags of sterile water were available. She did not see red lettering on the bag that stated “Pharmacy Bulk Package, Not For Direct Infusion” because the pharmacy label was on the opposite side of the bag. Another nurse noticed the statement and stopped the infusion. The patient experienced a hemolytic reaction and acute renal failure, and died after 550 mL had infused.

Error Related to Packaging, Labeling, and Storage

Bags of sterile water, especially 1 L size bags, can look like and be confused with other IV solutions. For example, a 1,000 mL bag of sterile water for injection was mistakenly dispensed by pharmacy to a dialysis unit and administered intravenously to a patient instead of a 1,000 mL bag of 0.9% sodium chloride injection.³ The two products looked similar despite a red, boxed warning under the name on the bag of sterile water (see Figure 1). The IV fluids were obtained by a pharmacy technician, checked by a pharmacist, delivered to the dialysis unit, and later taken from stock and administered by the dialysis nurse. The error was caught after 400 mL was administered.

Sterile water bags are also being stocked in patient care areas. A pediatric patient was ordered 0.9% saline, according to a PA-PSRS report.

Normal saline solution was ordered as a fluid bolus; sterile water hung. Blood work was drawn, and no changes [were observed]. Sterile water in bags was removed from nursing units.

No harm was noted. In order to prevent this error from occurring again, the facility removed IV bags of sterile water from nursing units.

Hospital materials management departments may provide patient care areas with liter bags of sterile water. One hospital reported through the ISMP-U.S. Pharmacopeia Medication Errors Reporting Program that their purchasing department stocked automated dispensing cabinets (ADCs) with IV solutions.⁴ In one instance, a wholesaler mistakenly delivered 1 L bags of sterile water for injection instead of 5% dextrose solution. The error was not caught when the product was received nor when the ADC was restocked. A nurse accidentally retrieved and hung one of the sterile water bags. A physician discovered the error when investigating the patient’s complaint of discomfort at the IV site. Sterile water was also found hanging on another patient, but only a small volume had infused. Both patients suffered no permanent harm.

Emergency malignant hyperthermia boxes found in the operating room and postanesthesia care unit can be another source of sterile water bags. Based on a recommendation from the Malignant Hyperthermia Association of the United States, these boxes often are stocked with 1 L bags of sterile water to dilute dantrolene sodium for injection, a skeletal muscle relaxant used to treat malignant hyperthermia.^{5,6} Unused or partially used bags of the solution may find their way into IV stock or be hung as an IV solution during emergent treatment.

Respiratory therapy staff may also store or bring bags of sterile water to patient care units for humidification devices used with ventilators or continuous positive airway pressure (CPAP) devices. Humidification of inspired gases helps prevent ciliary damage as well as heat and water loss.^{7,8} While there are several ways to humidify the gases, a “wet” setup may require the use of a sterile water bag, which is attached to a humidification receptacle on the ventilator or CPAP device. For example, some units contain tubing that must be spiked into a water container with a traditional IV-like port (see Figure 2). This means that only

Figure 1. Sodium Chloride Solution (Left) and Sterile Water for Injection (Right)



Image provided courtesy of ISMP.

Figure 2. Sterile Water Bag Connected to a Humidification Unit



Image provided courtesy of ISMP.

bags of sterile water can be used with these specific units to provide the humidification.

Sterile water for inhalation is available in 250 mL, 500 mL, 1 L, 2 L, and 3 L bags that can be used for wet setups. Some of these bags not only look similar to other IV solutions, but they can also be attached to IV tubing (and may be listed for purchase as “IV solutions”). One hospital reported to ISMP that a respiratory therapist left a liter bag of sterile water for inhalation unwrapped in the patient’s room to replace the current bag attached to the ventilator.⁴ A nurse, responding to an IV pump’s low volume alarm, replaced the empty IV bag with the sterile water bag, believing it had been left as an IV replacement. The patient received 500 mL before the error was noticed, but he suffered no harm. Sterile water for inhalation bags also may be stored on respiratory supply carts, right next to IV fluids, or hanging on an IV pole so the nurse could change the bag at night (see Figure 3).

Risk Reduction Strategies

Sterile water for injection, inhalation, and irrigation (excluding pour bottles) has been added to ISMP’s List of High Alert Medications.⁹ ISMP encourages healthcare organizations and practitioners to establish special safeguards to reduce the risk of errors with high-alert medications. Below are a number of strategies that may be considered to reduce the risk of IV administration of free water or sterile water for injection.

- Alert practitioners to the danger—primarily hemolysis—of infusing sterile water. Educate clinicians about the physiology behind infusing hypotonic, isotonic, and hypertonic solutions, especially in relation to the patient’s electrolyte levels.²
- Develop protocols to guide safe and effective treatment of hypernatremia. Treatment of severe hypernatremia generally consists of infusions that contain smaller amounts of sodium to reduce

blood levels slowly. Too rapid correction of hypernatremia may result in cerebral edema, seizures, and possibly death.^{2,10,11}

- If concerns exist about using dextrose solutions, elevated blood sugars can be treated with insulin. If there are concerns about fluid volume, patients can be given diuretics.²
- Program the pharmacy computer system to provide an alert, “Use Only as a Diluent,” when these products are entered. Avoid offering sterile water for injection as a choice in prescriber order entry systems.²
- Clarify any order for sterile water with the prescriber as the order will likely will cause hemolysis.²
- Store sterile water bags away from medication supplies. Never allow IV compounding products to leave the pharmacy’s sterile compounding area. Segregate these solutions and store them with warnings to not distribute them outside the pharmacy.^{2,3}
- Affix auxiliary warnings to both sides of sterile water bags.
- Sterile water for injection is available in 2 L (or larger) containers for IV compounding. The difference in size of these larger bags can help reduce the risk of confusion with other 1 L IV solutions.³
- For emergency malignant hyperthermia boxes, some hospitals have replaced the 1 L sterile water bags with an adequate supply of 50 mL vials⁴ or 2 L bags of sterile water for injection.
- If a wet setup is considered necessary to humidify inspired gases, humidification units that do not require the use of sterile water bags can be considered. Some manufacturers offer wet humidification setups with self-contained plastic bottles of sterile water for inhalation, so bags of sterile water are not required. Heat and moisture exchangers, which are self-contained disposable units that do not require a continuous flow of water, are another option. If these alternatives are not possible, establish guidelines for safe storage and handling of the sterile water for inhalation bags.⁴
- Alert respiratory staff to avoid leaving bags of sterile water in medication rooms or patient rooms or hung on IV poles.⁴
- Special poles that attach to the ventilator for the purpose of hanging sterile water bags for use with humidification units are available from some manufacturers. Consider using them when possible.⁴
- Arrange for pharmacists and pharmacy technicians trained in safe drug storage to conduct regular rounds on patient care units, the respiratory department, and other areas where medications are stored or given so they can assess the storage of medications and solutions.⁴
- Review the list of items that patient care units can order manually or automatically through materials management. Ensure that pharmaceutical products

Figure 3. Sterile Water Bag On IV Pole



Image provided courtesy of ISMP.

(including sterile water bags) cannot be provided without prior pharmacy agreement and supervision.²

- Share information about these errors with purchasing staff to increase awareness of errors.²

Notes

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Self-Assessment Questions

1. Sterile water for injection is intended for all of the following EXCEPT?
 - a. Compound intravenous (IV) products
 - b. Prepare parenteral nutrition solutions
 - c. Infuse intravenously
 - d. Solubilize small quantities of drugs
2. Rapid correction of severe hypernatremia can result in all of the following EXCEPT?
 - a. Seizure
 - b. High-output renal failure
 - c. Cerebral edema
 - d. Death
3. Sterile water for injection can cause hemolysis when administered intravenously.
 - a. True
 - b. False
4. All of the following factors contribute to errors involving sterile water for injection or sterile water for inhalation EXCEPT?
 - a. Look-alike nature of bags of sterile water and other IV solutions
 - b. Knowledge deficit about the risks of IV administration of sterile water
 - c. Storage of bags of sterile water for injection in medication rooms or patient rooms
 - d. Humidification units with self-contained plastic bottles of sterile water for inhalation
 - e. Bags of sterile water for injection from emergency malignant hyperthermia boxes find their way into IV stock
5. All of the following steps would help to reduce the risk of inadvertent IV administration of sterile water EXCEPT?
 - a. Stock sterile water for injection, irrigation, and inhalation in 1 L bags
 - b. Store sterile water bags away from medication supplies
 - c. Develop protocols to guide safe and effective treatment of hypernatremia.
 - d. Avoid offering sterile water for injection as a choice in prescriber order entry systems
 - e. Pharmacists and pharmacy technicians trained in safe drug storage make regular rounds on patient care units, respiratory department, and other areas where medications are stored and given to assess the storage of medications and solutions

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